TABLE OF CONTENTS

SUMMARY

This pre-announced, routine, surveillance inspection of a medical device manufacturer and specification developer was conducted under Operation ID # 51413, and in accordance with Compliance Programs 7382.845B and 7881.011, Inspection of Medical Device Manufacturers. The previous inspection was conducted on 08/08-12/2013, and was classified NAI.

This firm manufactures sterile disposable medical device products as accessories/components to their radiological delivery system capital equipment medical devices. Additionally, this firm is the specification developer of these radiological delivery system medical devices, which are manufactured at this firm's O'Hara (Pittsburgh, PA) facility. During this inspection, management controls, corrective and preventive actions, production and process controls, and design controls were reviewed.

At the conclusion of this inspection, two discussion items were reviewed with firm management, which are fully explained in the General Discussion with Management section of this report. Management was cooperative and made no refusals, and no FDA Form 483 was issued.

ADMINISTRATIVE DATA

Inspected firm:	Bayer Medical Care, Inc.
Location:	1 Bayer Dr Indianola, PA 15051-9702
Phone:	412-406-3305
FAX:	
Mailing address:	1 Bayer Dr Indianola, PA 15051-9702

Dates of inspection: 1/4/2017-1/6/2017
Days in the facility: 3
Participants: **Katelyn A Staub-Zamperini, Investigator**

At the beginning of this inspection, credentials were presented and an FDA Form 482, Notice of Inspection, was issued to William E. Bullis, Vice President, who identified himself as the most responsible individual at this location.

HISTORY

This firm is owned by Bayer Healthcare, and is part of the Bayer Radiology group under Bayer's Pharmaceuticals Division. This firm is registered with the FDA as Bayer Medical Care, Inc. and operates as Bayer Medrad. Firm management provided an introductory presentation on the company overview and relationship with Bayer **(Exhibit # 1)**, and an additional introductory presentation detailing the local firm and product specifics **(Exhibit # 2)**.

This firm currently maintains approximately (b) (4) employees, and operates (b) (4) per day, five days per week. This firm's annual production of sterile disposable products is approximately (b) (4) syringes and approximately (b) (4) packaged disposables. Future FDA correspondence should be addressed to, William E. Bullis, Vice President, and sent to:

1 Bayer Drive
Indianola, PA 15051

INTERSTATE (I.S.) COMMERCE

This firm utilizes the distributor, (b) (4) located in (b) (4). Products are then further distributed throughout the United States, as well as internationally.

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

This firm maintains a medical device registration with the FDA as a specification developer, manufacturer, and complaint file establishment. This firm is the specification developer of radiological delivery system medical devices, which are manufactured at this firm's O'Hara (Pittsburgh, PA) facility. Additionally, this firm manufactures sterile disposable medical device products. **Page #s 11-15** of **Exhibit # 2** describe this firm's product lines, manufacturing capabilities, and plant profile.

Firm management provided an Operation Manual for a Medrad brand MRXperion MR Injection System **(Exhibit # 3)**, and an Instruction for Use document for a Medrad brand MRXperion MR Injection System Syringe Kit **(Exhibit # 4)**.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Dr. Heiko Kranz, Quality Business Partner Medical Devices, William E. Bullis, Vice President, Joseph Kridgen, Quality Product Steward, Govardhan Singh, Alynell Castro-Diaz, Swapneel

Eklahare, Ryan Campbell, George Siddoway, Brandis Paull, John Dolinar, Denise Caldwell, Julia Mitchell, and Lisa Ewing, were all present during the close-out discussions and at various parts of this inspection, and provided relevant information. Joseph Kridgen, Quality Product Steward, was present for this entire inspection.

William (Bill) Bullis, Vice President, is the most responsible individual at this firm, and is responsible for all day-to-day operations. **Page #s 4-7** of **Exhibit # 1** and **page # 4** of **Exhibit # 2** contain various corporate, quality, and manufacturing organizational structures.

MANUFACTURING/DESIGN OPERATIONS

During this inspection, management controls, design controls, production and process controls, and corrective and preventive actions were reviewed. Inspectional coverage of each subsystem is as follows:

Management Controls: Management review and internal audit standard operating procedures were reviewed. Documentation of completion of both management review meetings and internal audits was also observed.

Design Controls: The design history file of the Stellant (b) (4) was reviewed, including design changes and component drawings. Verification and validation activities related to the Experion MR Injector and associated disposable products were reviewed, specifically disposable product functionality, design and construction, and the user interface.

Production and Process Controls: Component specifications and incoming inspection activities were reviewed. Manufacturing and production standard operating procedures were reviewed, including in-process and finished product acceptance criteria instructions and syringe kit reprocessing procedures. Various device history records to document the observed procedures were followed and adhered to were also reviewed.

Corrective and Preventive Action: Complaint handling, MDR reporting, and Corrective and Preventive Action standard operating procedures were reviewed. Complaint files, MDR reports, and CAPA files were also reviewed.

Two discussion items were reviewed with firm management, which are fully explained in the General Discussion with Management section of this report.

GENERAL DISCUSSION WITH MANAGEMENT

During the close-out meeting, medical device reporting activities were discussed. I reiterated to firm management that MedWatch forms should be completed accurately when submitting medical device

reports, specifically all dating, such as date form submitted, date firm aware, etc. I further discussed the need for accurate form submission, but discussed that it appeared as though medical device reports were being submitted when required and in a timely fashion.

Additionally, I discussed the use of rejected components during the manufacturing process. This firm uses an (b) (4) as a component of their Stellant CT device. This firm fails (b) (4) of these (b) (4) components during incoming inspection for not meeting specifications, but then continues to use these components as an accessory to their Stellant CT devices. Firm management explained that the (b) (4) products fail incoming inspection because they do not arrive with the required software. Once these components fail incoming inspections, the specified software is loaded onto these components, by this firm, and then used as an accessory to their Stellant CT devices. I discussed with firm management that they have created a routine practice of utilizing failed, nonconforming components, but also discussed how eventually the correct, specified software is loaded onto these (b) (4) products before finished product testing and release.

EXHIBITS COLLECTED

1 Exhibit 1, Introductory Presentation, 11 pages
2 Exhibit 2, Introductory Presentation, 18 pages
3 Exhibit 3, Operation Manual, 96 pages
4 Exhibit 4, Instructions for Use, 10 pages

ATTACHMENTS

1 FDA Form 482, Notice of Inspection, 3 pages

3/8/2017

X Katelyn A Staub-Zamperini

Katelyn A Staub-Zamperini
Investigator
Signed by: Katelyn A. Staub-zamperini -S